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# Summary Information

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K001885.

| | | |
|---|---|---|
| 1. | **Submitter name, address, contact** | Ortho-Clinical Diagnostics, Inc.<br>100 Indigo Creek Drive<br>Rochester, New York 14626-5101<br>(716) 453-4041<br><br>Contact Person: Marlene A. Shulman |
| 2. | **Preparation date** | Date Special 510(k) prepared: 20 June 2000 |
| 3. | **Device name** | Trade or Proprietary Name:<br>VITROS Chemistry Products BUN/ UREA Slides<br>VITROS Chemistry Products Calibrator Kit 1<br>Common Name : Urea nitrogen/ Urea test<br>Classification Name: Urea nitrogen test system ( 21 CFR 862.1770). |
| 4. | **Predicate device** | The VITROS Chemistry Products BUN/ UREA Slides (modified) and VITROS Chemistry Products Calibrator Kit 1 are substantially equivalent to the VITROS Chemistry Products BUN/ UREA Slides (current slide) and VITROS Chemistry Products Calibrator Kit 1. |

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**5. Device description**

The VITROS Chemistry System uses *Vitros* Slides to perform discrete chemistry tests on body fluid specimens. All reactions necessary for a single quantitative measurement take place within the multi-layered analytical element of a *Vitros* Slide.

The system is comprised of two main elements:

1. The VITROS Chemistry Products range of chemistry products (in this case VITROS Chemistry Products BUN/ UREA Slides, VITROS Chemistry Products Calibrator Kit 1, which are combined by the VITROS Chemistry System to perform the VITROS BUN/ UREA test.

2. The VITROS Chemistry System – instrumentation, which provides automated use of the chemistry slides. Multiple VITROS Chemistry Systems were cleared for market by separate 510(k) pre-market notifications (K890928, K890929, K922072, K946090 and K922072).

Common reagent used by the VITROS System. The VITROS Chemistry Products 7% BSA was cleared by a previous 510(k) pre-market notification (K903071).

The VITROS Chemistry System and Calibrators are dedicated specifically for use only with the VITROS Chemistry Products range of products.

**6. Device intended use**

VITROS BUN/ UREA Slides
For in vitro diagnostic use only.
VITROS BUN/ UREA Slides quantitatively measure urea nitrogen (BUN/ UREA) concentration in serum, plasma and urine.

VITROS Calibrator Kit 1
For in vitro diagnostic use only.
VITROS Calibrator Kit 1 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of BUN, Ca, CREA, GLU, LAC, Li, Mg, PHOS, SALI, THEO and URIC.

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**7. Comparison to predicate device**

The VITROS Chemistry Products BUN/ UREA Slide (modified) and VITROS Chemistry Products Calibrator Kit 1 are substantially equivalent to VITROS Chemistry Products BUN/ UREA Slide and VITROS Chemistry Products Calibrator Kit 1 which were cleared by the FDA for in vitro diagnostic use.
BUN/ UREA Slide: (K961196, May 15, 1996, for serum and plasma and K771245, October 7, 1977 for urine).
Calibrator Kit 1: (K922072, July 19, 1992).

Table 1 lists the characteristics of the tests performed using the VITROS BUN/ UREA Slide (modified) and the VITROS BUN/ UREA Slide(current).

**Table 1 List of Slide Characteristics: Comparison to Predicate Device**

| Device Characteristic | New Device VITROS BUN/ UREA Slide (Modified) | Predicate Device VITROS BUN/ UREA Slide (Current) |
|---|---|---|
| Sample volume | 5.5 µL | 10 µL |
| Quantity of Reactive Ingredients per slide (test) | Urease (jack beans, E.C.3.5.1.5) 1 U, N-propyl-4-(2,6-dinitro-4-chlorobenzyl)-quinolonium ethane sulfonate (ammonia indicator) 231 µg | Urease (jack beans, E.C.3.5.1.5) 9 U, N-propyl-4-(2,6-dinitro-4-chlorobenzyl)-quinolonium ethane sulfonate (ammonia indicator) 500 µg |
| Concentrations of Slide Reactive Ingredients per cm-squared | No Change. | Urease (jack beans, E.C.3.5.1.5) 1.2 U, N-propyl-4-(2,6-dinitro-4-chlorobenzyl)-quinolonium ethane sulfonate (ammonia indicator) 260 µg |
| Intended Use | No change. | For in vitro diagnostic use only.<br>VITROS BUN/ UREA Slides quantitatively measur BUN concentration in serum, plasma and urine. |
| Basic principle | No Change. | Dry, multilayered slide utilizing reflectance spectrophotometry |
| Sample type | No Change. | Serum , plasma , urine |
| Assay Range<br>Serum, Plasma<br>Urine | No Change. | <br>2.0- 120.0 mg/ dL<br>2.0- 120.0 mg/ dL (42- 2520 mg/dL without x21 dilution) |
| Instrumentation | No Change. | VITROS 250, 500, 750 and 950 Series Analyzers |
| Incubation time and temperature | No Change. | Approximately 5 minutes at 37°C |

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**8. Conclusions**

The information presented in the pre-market notification demonstrate that the performance of the VITROS BUN/ UREA Slides (modified) for use with human serum, plasma and urine is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured urea nitrogen values spanning the assay range.

The information presented in the premarket notification provide a reasonable assurance that the VITROS BUN/ UREA Slides (modified) for use with human serum, plasma and urine is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 0 2000

Ms. Marlene A. Shulman
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K001885
Trade Name: VITROS Chemistry Products BUN/UREA Slides
VITROS Chemistry Products Calibrator Kit 1
Regulatory Class: II
Product Code: CDN
Dated: June 20, 2000
Received: June 21, 2000

Dear Ms. Shulman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Statement of Intended Use



**510(k) Number (if known):** K001885

**Device Name:**

VITROS Chemistry Products BUN/ UREA Slides
VITROS Chemistry Products Calibrator Kit 1

**Intended Use:**

VITROS Chemistry Products BUN/ UREA Slides
For in vitro diagnostic use only.
VITROS BUN/ UREA Slides quantitatively measure urea nitrogen (BUN/ UREA) concentration in serum, plasma and urine.

VITROS Calibrator Kit 1
For in vitro diagnostic use only.
VITROS Calibrator Kit 1 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of BUN, Ca, CREA, GLU, LAC, Li, Mg, PHOS, SALI, THEO and URIC..

**Summary and Explanation of Test:**

The major pathway of nitrogen excretion is in the form of urea that is synthesized in the liver, released into the blood, and cleared by the kidneys. A high serum urea nitrogen occurs in glomerulonephritis, shock, urinary tract obstruction, pyelonephritis, and other causes of acute and chronic renal failure. Severe congestive heart failure, hyperalimentation, diabetic ketoacidosis, dehydration, and bleeding from the gastrointestinal tract elevate urea nitrogen. Low urea nitrogen often occurs in normal pregnancy, with decreased protein intake, in acute liver failure, and with intravenous fluid administration.[1]

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001885

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)